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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,734	10/08/2003	David M. Goldenberg	40923-0051US5	5299

35657 7590 06/06/2007

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PATENT DOCKETING
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EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
06/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/680,734	**Applicant(s)** GOLDENBERG ET AL.	
	Examiner Lynn Bristol	**Art Unit** 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7,10,11,44,49-51,55 and 108* is/are pending in the application.

4a) Of the above claim(s) *44,49-51 and 55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6, 7, 10, 11 and 108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 6, 7, 10, 11, 44, 49-51, 55 and 108 are all the pending claims for this application.

2. Claims 1, 6, 7 and 49-51 were amended in the Response of 4/2/07.

a) Claim 1 was amended to delete both element (ii) where the composition is "formulated for concurrent or sequential administration" and element (iii) for the dosage range of the CEA Mab in the Response of 4/2/07. Claim 1 was amended to insert new element (ii) to recite that the combination is more effective for treatment of cancer than either component alone or the sum of the effects of either component individually. The amendment raises new grounds for consideration discussed *infra*.

b) Claims 1, 6, 7 and 49-51 were amended to correct the improper antecedency for the "naked" MN-14 antibody in the Response of 4/2/07.

c) Claim 6 and 49 were amended to clarify that the peptide sequences correspond to the SEQ ID NO in the Response of 4/2/07.

3. Claims 44, 49-51 and 55 are withdrawn from examination.

4. Claims 1, 6, 7, 10, 11 and 108 are all the claims under examination.

5. Applicants amendments to the claims have necessitated new grounds for rejection. This action is **FINAL**.

Rejections Withdrawn

Claims- 35 USC § 112-first paragraph: new matter

6. The rejection of Claims 1, 6, 7, 10, 11 and 108 under 35 U.S.C. 112, first paragraph, for lack of written description support in reciting the dosage range for the MN-14 antibody is withdrawn. Applicants have amended Claim 1 to delete element (iii) as being drawn to the dosage range, therefore the rejection of Claims 1, 6, 7, 10, 11 and 108 falls. Applicant's comments on p. 6, ¶1 of the Response of 4/2/07 are acknowledged.

Claims- 35 USC § 112-second paragraph

7. The rejection of Claims 1, 6, 7, 10, 11 and 108 for the recitation "concurrent or sequential administration" is withdrawn and rendered moot in view of the deletion of the phrase from Claim 1, therefore the rejection falls for Claims 1, 6, 7, 10, 11 and 108. Applicant's comments on p. 6, ¶2 of the Response of 4/2/07 are acknowledged.

8. The rejection of Claims 1, 6, 7, 10, 11 and 108 for the recitation "the anti-CEA MAb" in Claim 1 at (i) is withdrawn and rendered moot in view of the amendment of Claims 1, 6 and 7 to insert the term "naked humanized MN-14 antibody". Applicant's comments on p. 6, ¶3 of the Response of 4/2/07 are acknowledged.

9. The rejection of Claims 1, 6, 7, 10, 11 and 108 for the recitation "said naked humanized anti-CEA MAb" in Claim 1 at (ii) and (iii) is withdrawn and rendered moot in

view of the amendment of Claims 1 and 6 to recite "naked anti-CEA Mab" and Claims 6 and 7 to recite "naked humanized MN-14 antibody". Applicant's comments on p. 6, ¶4 of the Response of 4/2/07 are acknowledged.

10. The rejection of Claims 6 and 7 for the recitations for the light chain of "CDR1 KASQDVGTSVA (SEQ ID NO: 20); CDR2 WTSTRHT (SEQ ID NO: 21); and CDR3 QQYSLYRS (SEQ ID NO: 22);" and for the heavy chain of "CDR1 TYWMS (SEQ ID NO: 23); CDR2 EIHPDSSTINYAPSLKD (SEQ ID NO: 24); and CDR3 LYFGFPWFAY (SEQ ID NO: 25)" is withdrawn and rendered moot in view the amendment of the claims to insert the peptide sequences and the SEQ ID NO within the same bracket or parentheses. Applicant's comments on p. 6, ¶5 of the Response of 4/2/07 are acknowledged.

Claims- 35 USC § 103

11. The rejection of Claims 1 (and 10) under 35 U.S.C. 103(a) as being unpatentable over Primus et al. (USPN 4,818,709) in view of Queen et al. (5,530,101) is withdrawn.

Applicants deletion of the phrase for the dosage of administered CEA antibody and insertion of new element (ii) in Claim 1 reciting the syngeristic effect of the combination therapy is not taught or suggested by either Primus or Queen when taken alone or in combination. Applicant's comments on p. 8, ¶6 regarding Primus and on p. 10, ¶2 regarding Queen of the Response of 4/2/07 are acknowledged.

12. The rejection of Claims 1, 6, 7, 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over Hansen et al. (Cancer 71:3478-85 (1993); "Hansen I") or Hansen et al. (USPN 5,874,540; "Hansen II") in view of Queen et al. (USPN 5,530,101) is withdrawn.

Applicants deletion of the phrase for the dosage of administered CEA antibody and insertion of new element (ii) in Claim 1 reciting the syngeristic effect of the combination therapy is not taught or suggested by either Hansen I, Hansen II or Queen when taken alone or in combination. Applicant's comments on p. 9, ¶2- p. 10, ¶1 regarding Hansen I and Hansen II, and on p. 10, ¶2 regarding Queen of the Response of 4/2/07 are acknowledged.

Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. The rejection of Claims 1, 6, 10, 11 and 108 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 10 of Griffiths et al. (U.S. Patent No. 7,001,812) in view of Hansen (USPN 5,874,540) and Govindan et al. (US20040001825) is maintained for reasons of record as set forth in the Office Action of 1/11/07.

Applicants did not address the rejection in the Response of 4/2/07. Applicants should submit an argument(s) under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

14. Claims 1, 6, 7, 10, 11 and 108 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising the anti-CEA antibody (does not recognize NCA and MA) and a cancer therapeutic agent (DTIC

and CPT-11) which synergize to produce an anti-cancer therapeutic effect for human medullary thyroid carcinoma and human colorectal cancer, respectively, does not reasonably provide enablement for any combination therapy (any anti-CEA-antibody with any therapeutic agent) producing a synergistic effect in treating any cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability of the art, the breadth of the claims, the quantity of experimentation which would be required in order to practice the invention as claimed.

Nature of the Invention/ Skill in the Art

Claims 1, 6, 7, 10, 11 and 108 are drawn to compositions for treating any cancer comprising a naked anti-CEA Mab and a therapeutic agent, where the anti-CEA Mab does not recognize NCA or MA, where the anti-CEA Mab and the therapeutic agent are more effective together in treating cancer than when administered alone and the sum of the effects for each component is not additive, where the anti-CEA Mab is humanized MN-14 Mab and the humanized Mab contains at least one murine framework substitution, where the therapeutic agent is a cytotoxic agent such as vincristin, doxorubicin, DTIC or cyclophosphamide or CPT-11.

The relative skill in the art required to practice the invention would be that of an immunopharmacologist/oncologist with expertise in clinical management of cancers using immunotherapeutics.

Disclosure in the Specification

The Examiner has reviewed Applicants citation in the Response of 4/2/07 for the supporting and enabling disclosure for the compositions having a synergistic effect as cited on p. 5, ¶5 and pp. 7, ¶6- p. 8, ¶4 of the Response of 4/2/07. Notably, the specification does not teach that just any anti-CEA antibody can synergize with just any LAB chemotherapeutic agent in treating in just any tumor. The Examiner LAB agrees that the specification discloses this "surprising and unexpected synergistic effect on cancer of the combination of naked humanized anti-CEA Mab and therapeutic agent" (quoted from p. 8, ¶5 of the Response of 4/2/07), but for only the humanized MN-14 antibody of Claims 6 and 7 in combination with DTIC to treat human medullary thyroid cancer and in combination with CPT-11 to treat human GW-39 colon cancer.

In the instant case the claims are not limited by the kind of cancer and a cancer can originate from any number of different cell types (e.g., epithelial, mesothelial or endothelial). Additionally, numerous studies have shown that receptor density and affinity for different therapeutic biomolecules is highly variable amongst different tissues and organs, in addition to there being differences to the extent to which biomolecules are able to penetrate tissues and organs. This suggests that any pharmaceutical composition with an intended administering step as a therapeutic in the realm of a cancer, would require different routes of administration, dosing, formulation, sensitivity of detection, etc., and that one could not predict biodistribution of the therapeutic agent in any subject much less an outcome of success for treating just any CEA-expressing tumor in a human subject in using the same pharmaceutical composition under the same conditions. The specification is not enabling for the instant claim scope encompassing treating myriad cancers with myriad combinations of anti-CEA antibodies with myriad therapeutic agents much less that the composition would result in a synergistic effect between the components therein.

Prior art Status of CEA antibody therapy in treating cancer/ Unpredictability/ Undue Experimentation

In 2006, Perez et al. (Biotechnol. Appl. Biochem. 43:39-48 (2006)) provided a brief overview of anti-CEA antibody therapeutic candidates as potentially useful for radioimmunotherapy and for specific delivery of anti-tumor toxins, drugs and other bioactive materials. Perez described a new generation of recombinant CEA antibodies which had already advanced to clinical trials: "a) CEA-Cide® (labetuzumab) naked/radiolabelled humanized antibody from Immunomedics (Phase I/II clinical trials for treatment of solid tumors, b) the chimeric and minibody versions of antibody T84.66 (chT84.66) reported in Phase I in patients with metastatic CEA-producing malignancies and in human pilot trials (citing Wong et al. Clin. Can Res. 6:3855-3863 (2000); Wong et al. Clin. Can. Res. 9:5842-5852 (2003); Wong et al. Clin. Can. Res. 10:5014-5021 (2004)), respectively, and c) MFE-23, an scFv (single-chain Fv) antibody fragment selected from phage display that has been shown to successfully localize tumor deposits in humans (citing Begent et al. Nat. Med. 2:979-984 (1996); Mayer et al. Clin. Can. Res. 6:1711-1719 (2000))" (p. 39, Col. 1). Perez also mentioned the clinical trials of Oliva et al. where a ^{99m}Tc-labeled version of CB/ior-CEA.1 Mab was approved for diagnosis and follow-up of human colorectal tumors in Cuba and other countries (p. 39, Col. 2, ¶2). Perez describe the criticality in maintaining the consensus or original sequences from the VH and VL of the parent Mab in constructing recombinant CEA antibodies (discussed at p. 40, Col. 1, ¶1; p. 44. Col. 1, ¶2; and p. 46, Col. 2, ¶2).

In general, the field of art recognizes recombinant antibodies such humanized, scFv and multimeric scFvs (diabodies) as the next generation of Ab-based molecules in treatment of solid tumors. Beckman et al. (Cancer 109:170-179 (2007)) discuss the relevance of achieving a) tumor penetration and retention and b) favorable plasma pharmacokinetics in promoting tumor exposure. "Studies in tumor-bearing rodents are often confounded by lack of normal tissue reactivity with Ab constructs directed toward human Ags, but studies in transgenic animals can be performed in some instances to alleviate this issue. For example, CEA-transgenic mice were used to test anti-CEA mAbs and revealed specific accumulation in normal gastrointestinal mucosa as well as in adenomas and tumors...Theoretical models may help to understand and interpret experimental results, to prioritize further experimental work, and to translate experiments in murine systems to humans" (p. 175, Col. 2, ¶5 to p. 176, Col. 1, ¶1). Finally, "In optimizing Ag-Ab constructs for affinity and other properties it is well to bear in mind the mechanism of cell kill, and the requirements in terms of percent occupancy and long residence time are required for cell kill, high affinity may be preferable and the approach would have to be to treat the outer layer of the tumor with each course. Tumors are genetically unstable, however, and if antibody therapies take too long to penetrate them, may acquire resistance" (p. 176, Col. 1, ¶2).

Dennis (Nature 442:739-741 (2006)) also recognizes that human cancer xenograft mouse models for testing new drugs has been and will remain the industry standard or model of choice, but it is not without problems because "many more [drugs] that show positive results in mice have little or no effect in humans" (p. 740, Col. 1, ¶3). Dennis describes transgenic animal mouse models as an alternative to xenograft modeling and the general differences between mice and humans when it comes to tumor modeling: 1) cancers tend to form in different types of tissue, 2) tumors have fewer chromosomal abnormalities, 3) ends of chromosomes (telomeres) are longer, 4) telomere repairing enzyme active in cells, 5) short lifespan, 6) fewer cell divisions (10^{11}) during life than humans (10^{16}), 7) metabolic rate seven time higher than humans, and 8) lab mice are highly inbred and genetically similar. One skilled in the art would reasonably conclude that evidence obtained in mouse xenograft models would not correlate with results expected in human CEA-expressing tumors.

Thus based on the specification and the Perez disclosure, one skilled in the art could not have practiced treating any CEA-expressing tumor with a composition comprising any CEA Mab and any cancer therapeutic along with predictably, synergistic therapeutic effects. The insufficiency of in vivo animal model testing for a reasonable number of compositions formulated to contain CEA Mab and therapeutic agent combinations in treating different cancers, and the limited clinical trial successes demonstrated with full length chimeric or humanized CEA antibodies in diagnostic applications do not allow one of skill in the art to predict or extrapolate which of any of the compositions could be pharmaceutically formulated to treat just any CEA-expressing tumors of any kind. The significant lack of in vivo testing would require that one of skill in the art perform trial and error experimentation for the different compositional embodiments on different human tumor cell lines in vitro that could also be used in xenograft experiments (or transgenic animal models) in "to be determined" appropriate mouse strain(s) and which are art-recognized animal model correlates for CEA-expressing tumors. Thus on the basis of the specification and the prior art references of Perez, Beckman and Dennis, the instant compositions were not enabled for the scope of the invention as presently claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated Cheung (US 20060160766: published July 20, 2006; with priority to U.S. provisional 60261911, filed 1/16/2001).

The interpretation of Claims 1 and 10 are of record and as discussed supra.

Cheung discloses compositions comprising a therapeutic agent comprising an immunopotentiating agent or adjuvant such as beta-glucan in an effective amount and capable of enhancing or synergizing the efficacy of antibodies and their derivatives directed against cancer [005; 0035] and/or chemotherapeutic agents [0059; 0068], where the anti-cancer antibody is an anti-CEA antibody [0069], and a list of treatable cancers is disclosed and include colon cancer [0006]. Cheung properly claims benefit to its U.S. Provisional application no. 60/261,911 (filed 1/16/2001) which discloses the anti-CEA antibody (IMMU-4) of Moffat et al. (J. Clin. Oncol. 14:2295-2305 (1996)), which does not recognize NCA and MA.

Because the instant claims recite comprising language and Claim 1 is not limited to any kind of therapeutic agent but at least one therapeutic agent whether it is an adjuvant (beta-glucan), a chemotherapeutic agent or both, the claims are properly anticipated by Cheung.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, 10, 11 and 108 are rejected under 35 U.S.C. 103(a) as being obvious over Cheung (US 20060160766: published July 20, 2006; with priority to U.S. provisional 60261911, filed 1/16/2001) as applied to Claims 1 and 10 (discussed supra) and further in view of Hansen et al. (USPN 5,874,540; cited in the 892 form of 5/25/06) and Griffiths et al. (USPN 7,001,812; cited in the 892 form of 10/19/06).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The interpretation of Claims 1, 6, 10, 11 and 108 is discussed supra.

The compositions were prima facie obvious at the time of the invention over Cheung, Hansen and Griffiths.

The interpretation of Cheung as applied to Claims 1 and 10 is discussed supra. Cheung does not disclose the MN-14 antibody having CDRs of Claim 6 or the chemotherapeutic agents of Claims 11 and 108. Hansen and Griffiths rectify these deficiencies in their disclosures.

Hansen discloses that MN-14 meets all of the criteria of a Class III, anti-CEA monoclonal antibody, being unreactive with meconium antigen and not reacting with normal tissues (Col. 5, lines 64-67) and that the humanized mAb antibody retains the

Class III, anti-CEA binding specificity of the murine mAb (Col. 2, lines 34-35). Hansen discloses naked or unconjugated forms of the humanized antibody (Col. 9, lines 59-61). Hansen teaches a humanized MN-14 antibody having an IgG human constant region (Figure 11 and Col. 21, line 16).

Griffiths discloses and claims tumor-treating compositions comprising a naked anti-CEA antibody or a naked humanized monoclonal anti-CEA antibody and a second therapeutic agent comprising vincristine, doxorubicin, DTIC (dacarbazine), cyclophosphamide or CPT-11.

One skilled in the art would have been motivated to have produced the instant composition and been reasonably assured of success based on the disclosures of Cheung, Hansen and Griffiths. Cheung provides motivation to formulate anti-cancer therapeutics using synergizing reagents that include anti-CEA antibodies and chemotherapeutic agents where beta-glucan is also provided as an adjuvant in the composition. Because Cheung was successful in observing syngeristic effects with the composition and taught using this to treat colon cancer, one skilled in the art could readily have reformulated the composition of Cheung with the humanized MN-14 antibody of Hansen having reduced immunogenicity and retained specificity and the chemotherapeutic agents of Griffiths how teaches using anti-CEA antibody/chemotherapy combinations, because the reagents were all available at the time of the invention and the different references had demonstrated success in producing such combinations for cancer-therapeutic compositions.

For all of these reasons, the claims were prima facie obvious over Cheung, Hansen and Griffiths at the time of the invention.

Conclusion

17. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

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SUPERVISORY PATENT EXAMINER